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**NATIONAL COFFEE ASSOCIATION OF U.S.A., INC.**

15 Maiden Lane, Suite 1405  
New York, NY 10038-4003  
TEL: (212) 766-4007  
FAX: (212) 766-5815  
[www.ncausa.org](http://www.ncausa.org)

August 30, 2002

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Bioterrorism Preparedness  
Docket No. 02N-0277 Establishment and Maintenance of  
Records**

Dear Sir or Madam:

The National Coffee Association of USA (NCA) appreciates the opportunity to provide input on the development of regulations relating to and required pursuant to the Bioterrorism Act (Act).

NCA represents the US coffee industry, which generates \$18 billion annually sales and conducts \$3 billion in trade with 30 countries from Asia, Africa and Latin America. In addition to the more than one thousand roasters and importers, the industry is comprised of some 10,000 coffee cafés employing persons in every state and region. Through retail, restaurant and coffee café sales the industry serves 177 million consumers annually. NCA membership, consisting, in part, of exporters, importers and roasters, will be impacted by the Bioterrorism legislation and associated regulations.

The NCA strongly encourages the FDA to incorporate existing records and systems to the maximum degree possible in fulfilling the legislative mandate, as opposed to developing new record keeping requirements and processes. Further, it is imperative that considerable attention be given to cross-agency coordination, thereby increasing the probability of compliance from the onset. Maximizing the use of existing records and systems, and developing a high level of cross-agency synergy, between the

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regulations and operations of the various agencies, will greatly lessen the economic impact of the legislation for FDA and the industry, and lead to a greater level of security.

It is critical that when the Act becomes effective products already in the distribution chain be exempt from the applicable record keeping and registration requirements. In the case of coffee, it is not unusual for surplus stocks to be in storage for three to four years, or more, before processing. These stocks may be held in US warehouses or warehouses in producing nations. As a result, much of the information required in the record keeping provisions, for example country of origin or prior ownership, is non-existent. Failure to "grandfather" these products will have place tremendous economic burden on US coffee companies, with no corresponding security benefit accruing to the nation or consumers.

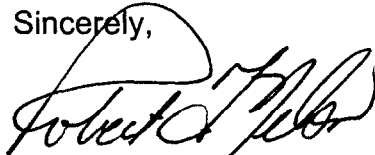
The NCA strongly urges FDA to define the first United States facility in which the imported product is held as the trigger for requirements mandated pursuant to the record keeping provision of the Act. In accordance with the Act, records must be maintained that allow FDA to identify the immediate previous source and immediate subsequent recipient of food and food packaging. The Act, however, allows for latitude in determining where this requirement formally starts for a US company. For example, is the record keeping requirement enacted when product is received by a US subsidiary in a foreign country, when a company takes ownership FOB upon the product being loaded on a shipping vessel, or when the product is first received in the United States? Again, NCA strongly urges FDA to adopt language that defines the first United States facility in which product is held as the trigger for record keeping requirements.

FDA is urged to give significant consideration to the treatment of products that are traded on a futures exchange as record keeping regulations are formulated. NCA suggests that it may be necessary to provide specific language clarifying record keeping requirements for commodities traded on futures exchanges. This especially holds true when taking into consideration the unique ownership/physical possession realities of exchange related transactions, including, but not limited to, the anonymity of the transaction between the buyer and seller, which prohibits the buyer from collecting information that may be required pursuant to Bioterrorism regulations.

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Again, the National Coffee Association appreciates the opportunity to submit comments. We look forward to the possibility of submitting subsequent comments following the publication of proposed regulations.

Sincerely,



Robert F. Nelson